



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,845	08/06/2003	Hiraku Murayama	011350-316	6514
21839 7590 12/20/2007 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER HOEKSTRA, JEFFREY GERBEN	
			ART UNIT 3736	PAPER NUMBER
			NOTIFICATION DATE 12/20/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com
debra.hawkins@bipc.com

Office Action Summary	Application No. 10/634,845	Applicant(s) MURAYAMA ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-15,17-31 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-15,17-31 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 09/21/2007 and 10/09/2007 have been entered.

Notice of Amendment

2. In response to the amendment filed on 10/09/2007, amended claim(s) 1, 3, 7-11, and 17-21, and new claim(s) 37-38 is/are acknowledged. The current rejections of the claim(s) 1, 3, 7-15, 17-31, and 36 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Objections

3. Claim 1 is objected to because of the following informalities: it appears that the positive recitations of "the distal side" in line 2, "the proximal side" in line 3, and "the outer periphery" in line 7 should read "a distal side", "a proximal side", and "an outer periphery". Appropriate correction is required.

4. Claim 3 is objected to because of the following informalities: it appears that the positive recitations of "the distal side" in line 3 and "the proximal side" in lines 3-4 should read "a distal side" and "a proximal side". Appropriate correction is required.

5. Claims 11 and 12 are objected to because of the following informalities: it appears that the positive recitations of "the thickness" in lines 1-2 should read "a thickness". Appropriate correction is required.

6. Claims 21 and 22 are objected to because of the following informalities: it appears that the positive recitations of "the thickness" in lines 1-2 should read "a thickness". Appropriate correction is required.

7. Claim 29 is objected to because of the following informalities: it appears that the positive recitations of "the average thickness" in lines 1-2 and "the range" in line 2 should read "an average thickness" and "a range". Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 3, 7-14, 17-24, 26-31, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al. (US 6,001,068, hereinafter Uchino) in view of Richardson et al. (US 6,494,847 B1, hereinafter Richardson).

10. For claims 1, 3, 9, 10, 26, and 36-38, Uchino teaches a guidewire (as best seen in Figures 1 and 3), comprising:

- a wire member (1) comprising a first distal wire (A) having a proximal end face (the right end face of wire A) butt resistance welded (column 7 line 60 – column 8 line 24) to a second proximal wire (B) having a distal end face (the left end face of wire B) to create a welded portion, wherein said first distal wire's proximal end face does not

axially overlap said second proximal wire's distal end face (as best seen in Figures 3(3));

- a cover layer (12) covering the welded portion and provided on an outer periphery of the wire member, said cover layer uniformly covering said welded portion (as best seen in Figure 3(4)), wherein said cover layer can be made of a metal with an elastic modulus that is less than that of said first wire (column 3 line 37 – column 4 line 65 and column 11 line 11 – column 14 line 67) or a resin comprising silicon resin (column 6 lines 19-65 and column 11 line 11 – column 14 line 67); and
- a distal-side cover layer (113) disposed distally from said cover layer (as best seen in Figure 1), made from a different material (and column 11 line 11 – column 14 line 67), and not overlapping said cover layer (as best seen in Figure 1),
- wherein the distal-side cover layer is capable of being formed in a manner such that the wire member is heated at a time of covering the wire member with the distal-side cover layer.

11. For claims 7-10, 12-13, 17-20, 22-23, and 27-28, Uchino teaches said cover layer and said distal-side cover layer being hydrophilic and reducing friction (column 12 lines 47-56).

12. For claims 14, 24, 30 and 31, Uchino teaches a composite guidewire comprising different wire materials including: said distal wire being a superelastic alloy wires and said proximal wire being stainless steel (column 3 line 37 – column 4 line 65 and column 11 line 11 – column 14 line 67).

13. Thus for claims 1, 3, 7-10, 12-14, 17-20, 22-24, 26-28, 30-31, and 36-38, Uchino teaches the claimed invention, as set forth above, except for expressly disclosing the guidewire having (a) a proximal-side cover layer disposed on a proximal side from the cover layer without an axial gap or overlap between the cover layer and the proximal-side cover layer or (b) the distal-side cover layer disposed on a distal side from said cover layer without an axial gap between the cover layer and the distal-side cover layer. Richardson teaches a guidewire (50) having (a) a proximal-side cover layer (62) disposed on a proximal side from a cover layer (66) without an axial gap or overlap between the cover layer and the proximal-side cover layer (as best seen in Figure 7) (column 4 lines 33-60) and (b) a distal-side cover layer (56) disposed on a distal side from said cover layer without an axial gap or overlap between the cover layer and the distal-side cover layer (as best seen in Figure 7) (column 4 lines 33-60). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Uchino and Richardson. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Uchino with the components as taught by Richardson to achieve the predictable results of configuring the mechanical properties of a guidewire to traverse tortuous vasculature.

14. For claims 11, 21, and 29, Uchino in view of Richardson teaches the claimed invention but does not disclose expressly the thickness of the cover layer and distal-side cover layer being 1 micron. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the guidewire as taught by Uchino in view of Richardson with the thickness of the cover layer and distal-side cover layer being 1 micron, because Applicant has not disclosed that the thickness of the cover layer and distal-side cover layer being 1 micron provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thickness of the metallic layer (column 12 lines 24-25) as taught by Uchino in view of Richardson, because it provides for connecting unlike materials when configuring a guidewire with varying mechanical properties and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Uchino in view of Richardson. Therefore, it would have been an obvious matter of design choice to modify Uchino et al to obtain the invention as specified in the claim(s).

15. Claims 15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Richardson and in further view of Reynolds et al (US 2003/0069521 A1, hereinafter Reynolds). Uchino in view of Richardson teaches the claimed guidewire, as set forth above, except for expressly disclosing the use of Co-Ni-Cr based alloy wire. Reynolds et al teaches the use of cobalt-based alloys in guidewire construction (paragraph 33). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods

with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Uchino in view of Richardson and Reynolds. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Uchino in view of Richardson with the components as taught by Reynolds to achieve the predictable results of configuring the mechanical properties of a guidewire to traverse tortuous vasculature.

Response to Arguments

16. Applicant's arguments with respect to claims 1, 3, 7-15, 17-31, and 36-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

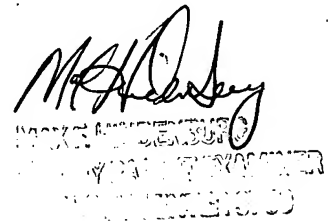
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/634,845
Art Unit: 3736

Page 8

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736



A handwritten signature, likely of the examiner, is written over a rectangular stamp. The signature is in cursive and appears to read 'M. Hoekstra'. The stamp contains text that is partially obscured by the signature but includes the words 'EXAMINER' and 'UNIT 3736'.